



SIS - REC/HRA Substantial Amendment 03 Cover Letter

Health and Social Care Research Ethics Committee B (HSC REC B)
Office for Research Ethics Committees Northern Ireland (ORECNI)
Lissue Industrial Estate West,
5 Rathdown Walk,
LISBURN,
BT28 2RF

30 June 2025

Study title: Randomised controlled trial of the clinical and cost-effectiveness of cervical spine immobilisation following blunt trauma (SIS trial)
REC reference: 22/NI/0173
Protocol number: 22IC7925
IRAS project ID: 316755

Dear HSC REC B

I am writing to you in relation to substantial amendment 03 for the above-mentioned trial. The following changes to the trial have been detailed in the amendment tool. Please see below for further clarification on the changes and reasons for these changes.

Minor changes to study documents - Patient Questionnaire booklets

Update to patient questionnaire booklet to include the approved licensed version of questionnaires.

SIS_ParticipantQuestionnaireBooklet_v4.0_12Jun2025

Creation of a Youth and Welsh version of the patient questionnaire booklet.

SIS_ParticipantQuestionnaireBookletYouth_v1.0_12Jun2025

SIS_ParticipantQuestionnaireBooklet_Welsh_v1.0_12Jun2025

Please be aware that 'SIS_ParticipantQuestionnaireBooklet_v3.0_03Jul2025' was not submitted to ethics in error, however version 4.0 as above now supersedes this version.

Kind Regards

Christina May (On behalf of the Chief Investigator - Prof Mark Wilson)
Clinical Trial Manager